

REMARKS

This responds to the Office Action mailed on December 1, 2006, and the references cited therewith.

Claim 79 has been cancelled. Claims 59-78 and 80-106 are therefore pending in the application. However, claims 59-73, 77 and 85-106 have been withdrawn from consideration. Thus, claims 74-76, 78, and 80-84 are now being examined in the application.

Claim 74 is amended. In particular, to clarify the language of claim 74, the language of claim 74 now specifies that the modified stem cells [are] coupled to an electrical interface and [are] adapted to be electrically coupled to endogenous tissue or cells. Support for the language of claim 74 can be found throughout the application and claims as originally filed, for example, in the specification at page 9, lines 4-11, page 12, lines 29-32, in the Examples and in original claims 1 and 2.

Applicant submits that no new matter has been added to the application.

§101 Rejection of the Claims

Claims 74-76 and 78-84 were rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. The Examiner has alleged that claims directed to in vitro or ex vivo modified stem cells “coupled via an electrical interface to endogenous tissue or cells,” is non-statutory subject matter.

Claim 74 is now directed to an implantable physiological or pathophysiological biosensor comprising: in vitro or ex vivo modified stem cells coupled to an electrical interface and adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject (etc.). Applicant submits that the claims contain no non-statutory subject matter.

The Examiner has stated that if the language “in vitro or ex vivo modified stem cells adapted to be coupled to an electrical interface” is used, than previously applied prior art rejections would be applied to the claims.

Applicant submits that the language of the current claims is free of any non-statutory subject matter and that the present claims are free of the prior art. In particular, U.S. Patent 5,750,376 to Weiss et al. discloses nothing whatsoever about a biosensor that includes both cells and an electrical interface. The Weiss et al. patent is limited to disclosure of neural stem cells

and provides no teaching on coupling such neural stem cells to an electrical interface. Contrary to allegations made by the Examiner, Weiss et al. at col. 22, lines 56-60 and at col. 23, lines 37-45, merely describes implantation of cells, not implantation of a biosensor that includes both cells and an electrical interface. Nor does the Weiss et al. patent disclose a biosensor (including cells and an electrical interface) that can monitor a chemical, physiological or pathophysiological function.

Applicant requests withdrawal of the rejection of claims 74-76 and 78-84 under 35 U.S.C. § 101.

§102 Rejection of the Claims

Claims 74-76 and 78-84 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent 6,238,429 to Markowitz et al. The Examiner alleges that Markowitz discloses all elements of the present claims.

Claim 74 is now directed to an implantable physiological or pathophysiological biosensor comprising: in vitro or ex vivo modified stem cells coupled to an electrical interface and adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject, wherein the in vitro or ex vivo modified stem cells can monitor a chemical, physiological or pathophysiological variable associated with the physiological or pathophysiological function of the subject and can produce a coagulation factor, serotonin, a growth factor, a hormone, or a receptor.

Applicant submits that Markowitz is limited to biological cables that span the totality of the distance between two tissues. Markowitz discloses nothing about a biosensor “implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject.” Accordingly, the Markowitz reference is missing at least one element of the present claims.

In addition, Markowitz is limited to *biological* cables – cables made of cells and other biological materials. Markowitz discloses nothing relating to electrical interfaces. For example, while the Examiner points to Markowitz FIGs. 5 and 6 allegedly disclosing a “device” that includes a wire, wire leads, tub, tubing or electronic pacemaker, Markowitz is actually limited to

cables of cells coated with fibrinogen or fibers (see Markowitz at col. 3, lines 20-30, which describe FIGs. 5 and 6). Thus, none of the following terms appear anywhere in the Markowitz disclosure:

- 1) “electrical interface”
- 2) “wire”
- 3) “tube”
- 4) “tubing”
- 5) “electronic”
- 6) “coagulation”
- 7) “factor” (appearing only in the title of a reference citation)
- 8) “serotonin”
- 9) “growth factor” (appearing only in the title of a reference citation)
- 10) “hormone”
- 11) “receptor”

In addition, Markowitz does not disclose the use of cells that can produce a coagulation factor, serotonin, a growth factor, a hormone, or a receptor.

Accordingly, the Markowitz patent fails to disclose at least three elements of the present claims. First, Markowitz fails to disclose a biosensor “implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject.” Second, Markowitz fails to disclose an electrical interface as claimed by the present claims. Third, Markowitz fails to disclose the use of cells that can produce a coagulation factor, serotonin, a growth factor, a hormone, or a receptor.

Applicant requests withdrawal of the rejection of claims 74-76 and 78-84 under 35 U.S.C. § 102(b).

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (516) 795-6820 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

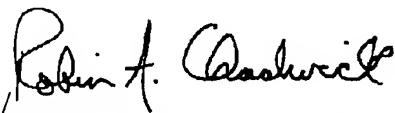
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 27th day of March 2007.

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